

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith.

Claims 1-15 are cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, and claims 16-31 are presented, based on the text throughout the application, including the Examples and the original claims. No new matter is added.

Claims 13 and 14 were rejected under Section 102(b) as anticipated by Damani. Claims 1-14 were rejected under Section 103(a) as unpatentable over Broadbeck in view of Tipton or Tipton in view of Broadbeck. And claims 1-15 were rejected under Section 103(a) as unpatentable over Broadbeck in view of Tipton in further view of Lewis. All of the rejections of the Final Office Action shall be addressed collectively, as follows:

The present claims are directed to eprinomectin-PLGA compositions and methods for the controlled release of eprinomectin. None of the cited documents teach or suggest eprinomectin-PLGA compositions or methods for the controlled release of eprinomectin.

Rather, by a Declaration herewith, it is shown that whether any one particular bioactive substance will function in a controlled release PLGA formulation is unpredictable, *i.e.*, that one cannot merely pull select teachings from documents to assert that a particular PLGA controlled release formulation is obvious.

In particular, the attached Declaration demonstrates that embodiments of the instant claims achieve suitable plasma levels of eprinomectin and are effective for treatment, prevention or control of parasites, whereas compositions containing another active ingredient – emamectin – do not achieve suitable plasma levels and are thus not effective, showing that one cannot predict whether a particular PLGA controlled release formulation will indeed function.

And therefore, the present invention is nonobvious, as it provides surprising and unexpected results.

In addition, it is noted that the claims employ the transitions "consisting essentially of" and "consists essentially of". The transitions "consisting essentially of" and "consists essentially of" occupy a middle ground between "comprises" and "consists of". They allow for elements not explicitly recited, but exclude elements that

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are found in the prior art or that affect a basic or novel characteristic of the invention. See, e.g., *In re Garnero*, 162 U.S.P.Q. 221 (C.C.P.A. 1969); *Ex parte Shepherd*, 185 U.S.P.Q. 480 (BOPA 1974); *Ex parte Hutchins*, 157 U.S.P.Q. 167 (BOPA 1967); see also *Zeigler v. Phillips Petroleum Co.*, 177 U.S.P.Q. 481 (5th Cir. 1973).

Thus, the claims, by their terms, distinguish from the documents cited.

Reconsideration and withdrawal of the rejections of the application and of the claims are respectfully requested.

If any issue remains as an impediment to allowance, an interview is respectfully requested, prior to issuance of any paper other than a Notice of Allowance, and it is further respectfully requested: that the USPTO recognize Thomas J. Kowalski, Reg. No. 32,147, Frommer Lawrence & Haug LLP, 745 Fifth Avenue, NY, NY 10151, tel 212-588-0800, fax 212-588-0500 as an Associate Attorney, especially to participate in such an interview; and, that the Examiner telephonically contact the undersigned to arrange a mutually convenient time and manner for such an interview.

In view of the amendments and remarks herewith and those of record and the Declaration herewith or to be filed shortly, the application is in condition for allowance. Favorable reconsideration of the application, reconsideration and withdrawal of the rejections, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

By: 

Mitul I. Desai  
Reg. No. 46,661  
Merck & Co., Inc.  
Patent Department, RY60-30  
P.O. Box 2000  
Rahway, NY 07065-0907  
Tel 732-594-3190

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